

## REMARKS

By this Amendment, claims 31-41 and 54-113 are pending in this application. Claims 40 and 41 have been withdrawn from further consideration as being allegedly drawn to non-elected species. Claims 1-30 and 42-53 have been cancelled. Claims 31-41 have been amended to more clearly define the subject matter recited in those claims. Claims 54-113 have been newly added. No new matter has been entered.

At least claims 31-39, 54-60, 63-79, 82-86, 91-95, 98-100, and 104-113 are readable on elected Group II and Species 1 and 3. Upon allowance of generic claims 31, 54, 76, and 91, claims 40, 41, 61, 62, 80, 81, 87-90, 96, 97, and 101-103, depending from respective one of generic claims 31, 54, 76, and 91 should be rejoined and entitled to further consideration.

For the reasons detailed below, Applicant respectfully requests reconsideration and withdrawal of the rejections set forth in the above-identified Office Action.

### 35 U.S.C. § 112, ¶2, Rejection

In the Office Action, the Examiner rejected claim 32 under 35 U.S.C. § 112, second paragraph, as being indefinite. In particular, the Examiner asserted that "the terminology 'basket-shaped spring valve' is ambiguous" and that "one having ordinary skill in the art does not know the intended boundaries of this limitation."

Although Applicant does not necessarily agree with the Examiner, Applicant has removed the objected-to language from the claims. Thus, this rejection is rendered moot. Reconsideration and withdrawal of this rejection is respectfully requested.

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35 U.S.C. § 102(e) Rejection Based on Greenhalgh

In the Office Action, the Examiner rejected claims 31-39 under 35 U.S.C. § 102(e) as being anticipated by Greenhalgh (U.S. Patent No. 6,494,909). In view of the foregoing claim amendments and the following reasons, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Independent Claim 31 and Its Dependent Claims

Independent claim 31, as amended, includes a combination of elements that is patentable over the disclosure of Greenhalgh. For example, claim 31 recites a medical esophageal stent having a valve including, among other things, "a generally tubular body [...] being sized and configured to be placed in an esophagus of a patient," and "a normally at least substantially closed valve formed of non-braided wires extended from the braided wires of the tubular body."

Greenhalgh does not disclose each and every element of the claimed invention. Greenhalgh discloses an endovascular valve 10 suitable for implantation within a lumen of a human vein. The valve 10 is formed by a plurality of flexible leaflets 24, 26 resiliently biased into a closed configuration. Greenhalgh, however, does not teach or suggest that a tubular body 16 of the valve 10 is "sized and configured to be placed in an esophagus of a patient." Instead, the valve 10 of Greenhalgh is merely intended to be implanted within a vein 12 of a patient, and there is no teaching or suggestion in Greenhalgh that neither the valve 10 nor the tubular body 16 is "sized and configured to be placed in an esophagus of a patient."

Moreover, Greenhalgh does not disclose a valve "formed of non-braided wires extended from the braided wires of the tubular body." Instead, the leaflets 24, 26 (i.e.,

allegedly construed by the Examiner as corresponding to the recited valve) of the valve 10 of Greenhalgh constitutes a distal portion of a tube 16 formed of interlaced filaments.

At least for these reasons, Greenhalgh fails to anticipate independent claim 31 and its dependent claims 32-41, 106, and 107. Thus, reconsideration and withdrawal of this ground of rejection is respectfully requested.

*New Independent Claim 54 and Its Dependent Claims*

New independent claim 54 includes a combination of elements that is patentable over the disclosure of Greenhalgh. For example, claim 54 recites a medical stent having a valve including, among other things, "a normally at least substantially closed valve formed of non-braided wires extended from the braided wires of the tubular body." For similar reasons set forth above in the discussion of claim 31, Greenhalgh does not disclose this recitation and therefore independent claim 54 and its dependent claims 55-63, 108, and 109 define novel and non-obvious subject matter over Greenhalgh.

*New Independent Claim 64 and Its Dependent Claims*

New independent claim 64 includes a combination of elements that is patentable over the disclosure of Greenhalgh. For example, claim 64 recites a medical stent having a valve including, among other things, "a normally at least substantially closed valve formed of non-braided wires extended from the braided wires of the tubular body" and "the non-braided wires being curled inwardly so as to form wires having a convex shape relative to an interior of the valve."

For similar reasons set forth above in the discussion of claims 31 and 54, Greenhalgh does not disclose "a normally at least substantially closed valve formed of non-braided wires extended from the braided wires of the tubular body," as recited in

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independent claim 64. In addition, Greenhalgh does not teach or suggest "the non-braided wires being curled inwardly so as to form wires having a convex shape relative to an interior of the valve." Not only are the leaflets 24, 26 of the valve 10 of Greenhalgh not formed of "non-braided wires," but Greenhalgh includes no teaching of the wires of the leaflets 24, 26 curling inwardly to form "a convex shape relative to an interior of the valve." Instead, the hand-drawn figures (see especially Figures 9 and 10), at best, show the wires forming leaflets 24, 26 in substantially straight configuration. Moreover, the text describes the leaflets 24, 26 as taking a "converging shape [that] resembles a duckbill." See col. 3, lines 53-59. A duckbill has a top and bottom in a substantially straight configuration. The text describes that the shape is attained "by flattening of the tube wall," (col. 3, lines 53-59; emphasis added), further suggesting the substantially straight configuration of the leaflets 24, 26. Clearly, nothing in the text of Greenhalgh discloses or suggests that the wires of leaflets 24, 26 assume "a convex shape relative to an interior of the valve," as claimed.

At least for these reasons, independent claim 64 and its dependent claims 65-69, 110, and 111 define novel and non-obvious subject matter over Greenhalgh.

*New Independent Claim 70 and Its Dependent Claims*

New independent claim 70 includes a combination of elements that is patentable over the disclosure of Greenhalgh. For example, claim 70 recites a medical esophageal stent having a valve including, among other things, "a generally tubular body [...] having a generally tapered body and being sized and configured to be placed in an esophagus of a patient," "a normally at least substantially closed valve formed of non-braided wires extended from the braided wires of the tubular body," and "the non-braided wires being

, curled inwardly so as to form wires having a convex shape relative to an interior of the valve.” For similar reasons set forth above in the discussion of claims 31, 54, and 64, Greenhalgh does not disclose these claim recitations. Independent claim 70 and its dependent claims 71-75, 112, and 113 therefore define novel and non-obvious subject matter over Greenhalgh.

*New Independent Claim 76 and Its Dependent Claims*

New independent claim 76 includes a combination of elements that is patentable over the disclosure of Greenhalgh. For example, claim 76 recites a medical esophageal stent having a valve including, among other things, “a generally tubular body [...] being sized and configured to be placed in an esophagus of a patient.” For similar reasons set forth above in the discussion of claims 31 and 70, Greenhalgh does not disclose this claim recitation and independent claim 76 and its dependent claims 77-90 therefore define novel and non-obvious subject matter over Greenhalgh.

*New Independent Claim 91 and Its Dependent Claims*

New independent claim 91 includes a combination of elements that is patentable over the disclosure of Greenhalgh. For example, claim 91 recites a medical stent having a valve including, among other things, “a normally at least substantially closed valve [...] including a valved end having an opening when the valve is in the normally at least substantially closed position.” Greenhalgh does not disclose this claim recitation. Instead, Greenhalgh discloses that the valve operates to prevent retrograde flow of blood by virtue of the functional shape of the tube 16 and that the valved end of the leaflets 24, 26 must be sufficiently biased to close reliably between pulses for the endovascular valve to operate effectively as a one-way valve. See col. 4, lines 34 - 65,

of Greenhalgh. Furthermore, in order to prevent retrograde blood flow through interstices formed between the filaments, the valve is provided with a silicone coating to seal the interstices. See the paragraph bridging between cols. 4 and 5 of Greenhalgh.

At least for these reasons, independent claim 91 and its dependent claims 92-105 define novel and non-obvious subject matter over Greenhalgh.

#### 35 U.S.C. § 102(b) Rejection Based on Brice

In the Office Action, the Examiner rejected claims 31-39 under 35 U.S.C. § 102(b) as being anticipated by Brice (French Patent Appln. Pub. No. 2 788 217). In view of the foregoing claim amendments and the following reasons, Applicant respectfully requests reconsideration and withdrawal of this rejection.

#### *Independent Claims 31 and 76 and Their Dependent Claims*

Each of independent claim 31, as amended, and new independent claim 76 includes a combination of elements that is patentable over the disclosure of Brice. For example, claim 31 recites a medical esophageal stent having a valve including, among other things, "a generally tubular body [...] being sized and configured to be placed in an esophagus of a patient." Claim 76 includes similar recitations.

Brice does not disclose each and every element of the claimed invention. Brice discloses a prosthetic heart valve 1 having a rigid expansible structure 2 and a valve structure 3 integrally formed with the expansible structure 2. Brice, however, does not teach or suggest that the valve structure 3 is "sized and configured to be placed in an esophagus of a patient," as recited in claims 31 and 76. A prosthetic heart valve is generally implanted in a heart of a patient in order to replace a natural cardiac valve of the patient. Application of such a prosthetic cardiac valve is distinctively different from

that of an esophageal stent and, therefore, the prosthetic heart valve 1 of Brice is neither sized nor configured to be placed in an esophagus of a patient.

At least for this reason, Brice fails to anticipate independent claims 31 and 76 and their respective dependent claims 32-41, 106, 107, and 77-90. Thus, reconsideration and withdrawal of this ground of rejection is respectfully requested.

*New Independent Claim 54 and Its Dependent Claims*

New independent claim 54 includes a combination of elements that is patentable over the disclosure of Brice. For example, Brice does not teach or suggest a medical stent having “a generally tapered tubular body,” distinct from the valve portion of the stent, as recited in claim 54. Instead, the prosthetic valve structure 1 of Brice has a straight tubular body 2. While Brice discloses that the body 2 may have a throttling median 34, 35, as shown in Figs. 3 and 4, the tubular body 2 does not form “a generally tapered tubular body.” At least for this reason, independent claim 54 and its dependent claims 55-63, 108, and 109 define novel and non-obvious subject matter over Brice.

*New Independent Claim 64 and Its Dependent Claims*

New independent claim 64 includes a combination of elements that is patentable over the disclosure of Brice. For example, Brice does not disclose, among other things, a medical stent having a valve including “non-braided wires [extended from the braided wires of the tubular body] being curled inwardly so as to form wires having a convex shape relative to an interior of the valve,” as recited in claim 64. Instead, each of the stiffeners 33 extending from a base 31 of the tubular body 4 forms a concave shape (i.e., just the opposite shape of the recited “convex shape”) relative to an interior of the valve, as best shown in Figs. 2a-2c. At least for this reason, independent claim 64 and

its dependent claims 65-69, 110, and 111 define novel and non-obvious subject matter over Brice.

*New Independent Claim 70 and Its Dependent Claims*

New independent claim 70 includes a combination of elements that is patentable over the disclosure of Brice. For example, claim 70 recites a medical esophageal stent having a valve including, among other things, “a generally tubular body [...] having a generally tapered body and being sized and configured to be placed in an esophagus of a patient” and “non-braided wires being curled inwardly so as to form wires having a convex shape relative to an interior of the valve.” For similar reasons set forth above in the discussion of claims 31, 54, and 64, Brice does not disclose these claim recitations and, therefore, independent claim 70 and its dependent claims 71-75, 112, and 113 define novel and non-obvious subject matter over Brice.

*New Independent Claim 91 and Its Dependent Claims*

New independent claim 91 includes a combination of elements that is patentable over the disclosure of Brice. For example, claim 91 recites a medical stent having a valve including, among other things, “a normally at least substantially closed valve [...] including a valved end having an opening when the valve is in the normally at least substantially closed position.” Brice does not disclose this claim recitation. Instead, as shown in Figs. 1c and 2c, Brice discloses a valve having a valved end that is completely closed when the valve is in its closed position. At least for this reason, independent claim 91 and its dependent claims 92-105 define novel and non-obvious subject matter over Brice.



### CONCLUSION

From the foregoing Amendment and remarks, Applicant respectfully requests the reconsideration of this application, and the timely allowance of all pending claims 31-41 and 54-113.

The Office Action contains a number of statements and characterizations regarding the claims and the related art. However, Applicant declines to subscribe to any statement or characterization in the Office Action, regardless of whether it is addressed above.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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